K123401 1/3

JAN 23 2013

510(k) Summary

Proprietary Name:	Gamma3 and T2 Recon Target Devices
Common Name:	Intramedullary Fixation Rod
Classification Name and Reference:	Intramedullary Fixation Rod 21 CFR §888.3020
Regulatory Class:	Class II
Product Codes:	87HSB: Rod, Fixation, Intramedullary and Accessory
For Information contact:	Estela Celi, Regulatory Affairs Specialist Stryker Trauma AG Bohnackerweg 1 CH-2545 Selzach Switzerland Phone: (201) 831-6461 Fax: (201) 831-3461 estela.celi@stryker.com
Date Prepared:	November 2, 2012

Description

This Traditional 510(k) submission is being supplied to the US FDA to address modifications made to the Gamma3 Target Device and addition of a new Distal Targeting Device to the Gamma3 (K043431) and T2 Recon Nail Systems (K102992) as well as the inclusion of the existing target devices in the Gamma3 and T2 Recon Nail Systems.

Intended Use

The Gamma3 Target Devices do not alter the intended use of the predicate Gamma3 Nail System as cleared in K043431. The indications for use for the subject device is provided below.

The Distal Targeting Devices do not alter the intended use of the predicate Gamma3 and T2 Recon Nail Systems as cleared in K043431 and K102992, respectively. The indications for use for the subject devices are provided below.

Indications

The line extension to the T2 Recon Nail System and Gamma3 Nail System does not alter the indications for use of the predicate system as cleared in its' respective premarket notifications.

The Gamma3 Target Devices are intended for use with the Trochanteric Nail or Long Length Gamma3 Nail.

The Gamma3 and T2 Recon Distal Targeting Devices are intended for use with the Long Length Gamma3 Nail and T2 Recon Nail System.

Gamma3 Nail System

The Trochanteric Gamma3 Nail is indicated for fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections, while the Long Length Gamma3 Nail inidcation may include fractures resulsting from trauma, nonunion, malunion, pathological fractures, impending pathological fractures, tumor resections and revision procedures.

T2 Recon Nail System

The T2 Recon Nail System indications include fixation of subtrochanteric, intertrochanteric, ipsilateral neck/shaft, communited proximal femoral shaft fractures, femoral fixation required as a result of pathological disease, and temporary stabilization of fractures of the femoral shaft ranging from the femoral neck to the supracondylar regions of the femur.

Summary of Technologies

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the following predicate devices and that the target devices as an accessory to the Gamma3 and T2 Recon Nail System does not alter the technology.

- K043431 – Gamma3 Nail System
- K102992 – T2 Recon Nail System

Non-Clinical Testing

Non-clinical laboratory testing and engineering evaluations were performed on the target devices to determine substantial equivalence. Testing and evaluations demonstrated that the subject target devices are substantially equivalent to devices currently cleared for marketing.

The following testing was performed:

- Conditioning
- Targeting Accuracy and Stiffness

Engineering Evaluations were completed for the following:

- Accomodation for 480mm Nails in Distal Targeting Device

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The Gamma3 Target Devices and the Gamma3 and T2 Recon Distal Targeting Devices are substantially equivalent to the predicate devices identified in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Stryker Trauma AG
% Howmedica Osteonics Corporation
Ms. Estela Celi
325 Corporate Drive
Mahwah, New Jersey 07430

Letter dated: January 23, 2013

Re: K123401
Trade/Device Name: Gamma3 and T2 Recon Target Devices
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 2, 2012
Received: November 28, 2012

Dear Ms. Celi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123401

Device Name: Gamma3 and T2 Recon Target Devices

The Gamma3 Target Devices are intended for use with the Trochanteric Nail or Long Length Gamma3 Nail.

The Gamma3 and T2 Recon Distal Targeting Devices are intended for use with the Long Length Gamma3 Nail and T2 Recon Nail System.

Gamma3 Nail System

The Trochanteric Gamma3 Nail is indicated for fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections, while the Long Length Gamma3 Nail inidcation may include fractures resulsting from trauma, nonunion, malunion, pathological fractures, impending pathological fractures, tumor resections and revision procedures.

T2 Recon Nail System

The T2 Recon Nail System indications include fixation of subtrochanteric, intertrochanteric, ipsilateral neck/shaft, communited proximal femoral shaft fractures, femoral fixation required as a result of pathological disease, and temporary stabilization of fractures of the femoral shaft ranging from the femoral neck to the supracondylar regions of the femur.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

2013.01.18 11:16:42 -05'00'